

THE U.S. EPA'S DRAFT ETS RISK ASSESSMENT

INTRODUCTION

When the Environmental Protection Agency (EPA) first released its draft risk assessment on environmental tobacco smoke (ETS) for public comment in June 1990, it created a significant scientific controversy.

The draft's conclusions, that ETS was a Group A or "known human" carcinogen and that 3,800 Americans die every year from lung cancer caused by exposure to ETS were strongly disputed by many scientists.

The vast majority of scientists who filed comments with the EPA on its draft report disagreed with the agency's conclusions, and even a member of the EPA's own Science Advisory Board stated publicly that classifying ETS as a known human carcinogen may be "rash".

And yet, the EPA are expected to confirm their conclusions in their final report. And already the figure of 3,800 American deaths a year has become an accepted 'scientific fact'. Amid such controversy, it is worth taking a closer look at the EPA's draft risk assessment on ETS and claimed health effects.

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THE DRAFT REPORT

The draft report was based on 24 published epidemiologic studies on lung cancer incidence among non-smokers married to smokers. It is the first risk assessment ever conducted by the EPA based entirely on epidemiologic evidence.

Of the 24 published studies, 19 report no statistically significant increased risk, including the nine US studies. The remaining five studies report risk ratios that are weak at best, all below 3.0 and well within the range epidemiologists consider difficult to interpret because of problems inherent in study design and conduct. These five studies were also conducted in countries outside the US and, according to some members of the scientific community, improperly controlled. The studies all suffer from a number of serious flaws, including:

Poor exposure classification

Exposure is based on reports of spousal smoking. There are no real measures of the actual existence or degree of non-smoker exposure.

Confounding Factors

Research indicates that smokers, and their spouses, tend therefore to have poorer diets, a reported contributor to lung cancer. Other factors include alcohol consumption, occupational exposures, exercise, genetic predisposition and socio-economic status. None of these "confounding factors" were well considered in these studies.

FAILURE TO FOLLOW EPA GUIDELINES

The draft report is solely based on epidemiology and involves all of the most difficult issues inherent in epidemiology - weak statistical associations, indirect and unreliable measures of exposure to ETS, extremely low levels of exposure and numerous possible sources of bias and confounding factors.

And yet, the EPA did not follow the recommendations of a panel of distinguished epidemiologists as to the limitations of using such data in making risk assessments. This panel was convened at the EPA's request to issue guidelines for the assessment of carcinogens based on such data.

The panel's recommendations, outlined in a 1986 EPA report, contained five criteria to assure that the data were adequate to reach conclusions, but none of these criteria were apparently applied to the EPA's draft ETS risk assessment.

Apparently, the agency is also applying its carcinogen classification guidelines inconsistently. As the attached chart shows, the EPA concluded in its recent draft risk assessment on exposure to electromagnetic fields (EMF) that such exposure could not be viewed as causing cancer. Yet the data base on EMF exposure was stronger in some respects than that for ETS. → (see comparison in Appendix II)

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THE REVIEW PROCESS

The draft report was reviewed at a meeting of the EPA's Science Advisory Board (SAB) on December 3 and 4, 1990.

The panel members were provided with copies of the draft as well as copies of the extensive scientific comments submitted to the agency. During the public presentations it became clear that a number of panel members were unfamiliar with the issues raised in the public comments and some even stated on record that they had not looked at the scientific comments.

The great majority of scientists who filed comments with the EPA were severely critical of the agency's conclusion. The SAB's own consensus was reached despite serious doubts expressed by many panel members about the adequacy of the data.

At the end of the review, the SAB's Chairman stated that, while the EPA had not "made the case" for concluding that ETS is a "known human" carcinogen, the consensus of the committee agreed with the EPA's conclusion.

The SAB's recommendations - that the EPA rewrite virtually everything in the draft report except the conclusions - have now gone back to the EPA.

The EPA has said that, in revising its risk assessment, it will consider studies published since the initial draft was completed. However, the most recent ETS-lung cancer study,[†] a large case control study of Chinese women, was never mentioned during the SAB's review, despite the fact that one of the co-authors was a member of the panel, nor was it provided for inclusion in the risk assessment's calculations.

The study reported no association between spousal smoking and lung cancer, in fact it reported a statistically significant inverse relationship.

When this study and two others omitted by the EPA are added to the EPA's meta-analysis* the results do not show that spousal smoking is statistically associated with the risk of lung cancer in non-smokers.

[†] Wu - Williams et al

* See Footnote: Meta-Analysis

CONCLUSION

A careful scientific review of the literature reveals that the EPA draft documents on ETS are an uncritical condensation of selectively chosen studies, subjected to a series of highly speculative adjustments seemingly to reach a "predetermined outcome".

There is a considerable body of scientific thought in Europe, as well as in the US, that places no credence in the EPA's conclusion. And there appears to be no way in which to apply the agency's own current carcinogen classification guidelines on the available data on ETS and reach the conclusion that the EPA seems to want to reach.

As far as the EPA's draft workplace policy guide is concerned, many of the same scientific concerns apply. Equally, since the agency's analysis concerned only ETS at home and not data on ETS in the workplace, workplace guidelines from the EPA are clearly inappropriate.

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APPENDIX I

A EUROPEAN PERSPECTIVE

The clear majority of scientific comments filed with the EPA on the draft report challenge the agency's conclusions. Among these comments are a considerable number of contributions from eminent European scientists:

- Professor B. Schn²¹ider, of the Institute of Biometry of the medical school in Hanover, Germany, reanalysed the data employed by the authors of the ETS epidemiologic studies and concluded that: "a valid statistical analysis does not reveal any significant association between ETS and any health risks".
- Petr Skrabanek, Senior Lecturer on Community Health at Trinity College, Dublin, questioned EPA's heavy reliance on its meta-analysis of epidemiologic studies (especially by Hirayama) carried out on Asian women: "Such women are unsuitable for studying the effects of ETS, given evidence of strong confounding factors and because even active smoking in these women has been only weakly associated with lung cancer and the majority of lung cancer cases are non-smokers". Further, he detected "serious unresolved problems of biological plausibility" in the EPA draft.
- UK statistician Peter Lee, to whose work the EPA draft made numerous references, provided an exhaustive analysis of every epidemiologic study conducted with respect to ETS exposure and lung cancer. The key flaws he detected in the EPA draft, which in his view made it "unacceptable", were its "overestimation of epidemiological in relation to dosimetric evidence"*, its "omission of relevant data and inclusion of inappropriate data in the meta-analysis of the epidemiological evidence", its "errors in adjustments for bias due to misclassification of smoking habits" and its "errors in applying the adjusted meta-analysis risk estimates".
- R.C.Brown of the Medical Research Council Toxicology Unit in the UK cautioned that the acceptance of the EPA draft's unfounded conclusions could lead to the misattribution to ETS exposure of many lung cancer cases that are in fact due to as yet unidentified causes.

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* See Footnote: Dosimetric Approach

- Professor Ragnar Rylander of the Department of Environmental Hygiene at the University of Gothenburg, Sweden pointed out that the average exposure to tobacco smoke constituents in ETS exposed individuals is exceedingly low, providing grounds for scepticism about a causal relationship with respect to lung cancer. He offered the judgement that: "the arguments for biological plausibility in the {EPA draft} unfortunately do not reflect a critical scientific evaluation of the critical toxicological and epidemiological concepts involved".
- Professor Guy Crepat, head of the Applied Biology Dept at the University of Burgundy, France, disputed the EPA draft's reliance on an assumed linear relation between the claimed cancer risk from ETS and the level of cotinine (a metabolite of nicotine) in the body fluids of non-smokers, and argued that such reliance leads inevitably to an overestimation of risk.
- UK pathologist F.J.C.Roe, formerly head of The Department of Experimental Pathology at the London Institute of Cancer Research, took the EPA draft to task for its "wholly unscientific and wholly invalid" use of meta-analysis and expressed the view that "the only safe conclusion that can be based on the available evidence is that it remains unclear whether there is any lung cancer risk from exposure to other people's tobacco smoke and if there is any such risk there is absolutely no reliable way to quantify it".

FOOTNOTES:

META-ANALYSIS

The controversial statistical tool of meta-analysis combines a number of studies to produce a single estimate of relative risk. It is generally used when studies standing alone lack a sufficient number of cases to justify any association. The EPA draft makes no effort to distinguish between US and non-US studies. The meta-analysis of the US studies considered in the EPA draft yields a result that is not statistically significant and therefore provides no basis for any prediction of risk.

DOSIMETRIC APPROACH

The EPA's standard method of risk assessment is the dosimetric approach. This method extrapolates to low exposures from effects reported in higher exposures. Using this approach the risk estimate for ETS is hundreds of times lower than the estimate from the EPA's review of the epidemiologic studies.

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APPENDIX II

STATE OF THE SCIENCE IN EUROPE

International and National health agencies throughout Europe have come to somewhat different conclusions on ETS than the EPA. Their conclusions have been more considered:

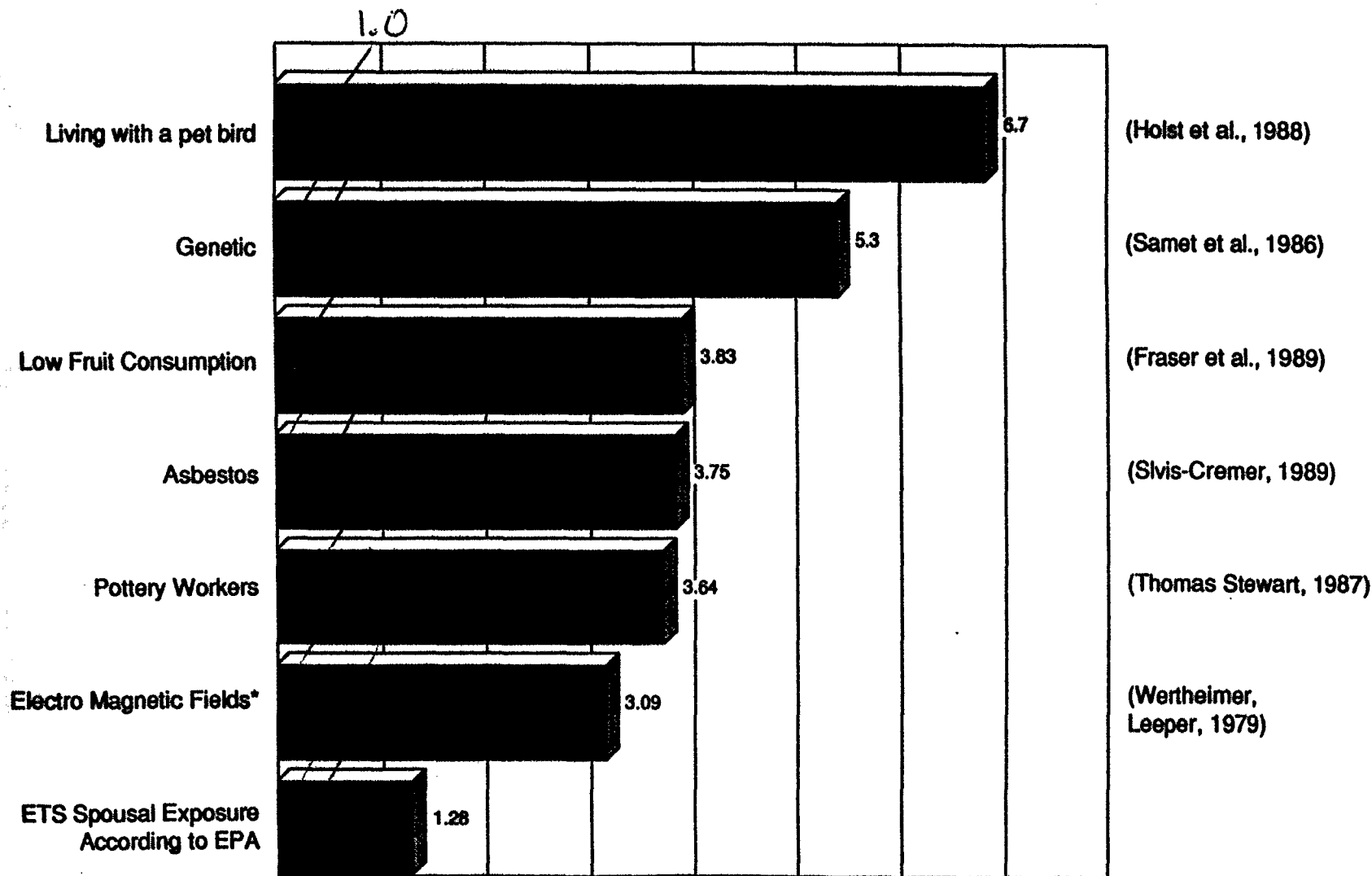
- The Committee of the Health Council of the Netherlands recently evaluated all the major articles and studies on ETS prior to June 1990 at the request of the Dutch government. The report concluded: "To evaluate the effect of exposure to ETS one has to rely mainly on the results of epidemiological research carried out among non-smokers. This kind of research is beset by methodological problems which may distort the outcome."

"The Committee would emphasise that the apparent increase in lung cancer risk could be partly due to flaws in the design of the epidemiological studies. As it is not known to what extent the results of the several studies are distorted, the Committee is of the opinion that quantitative estimation of the additional lung cancer risk of non-smokers exposed to tobacco smoke is not possible at present".

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Lung Cancer Relative Risks



* Childhood Cancer

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EMF - Electromagnetic Fields

"The association between cancer occurrence and exposure to either EFL or RF fields is not strong enough to constitute a proven causal relationship largely because the relative risks in the published reports have seldom exceeded 3.0 on both childhood residential exposures and in occupational situations."

"Both animal and in vitro studies are needed to discover the relevant exposure factors in their interaction and to gain some understanding of the mechanisms of action."

ETS - Environmental Tobacco Smoke

All studies used in the meta-analysis calculation have relative risks less than 3.0. The EPA calculated the relative risk for ETS (via meta-analysis) to be 1.28.

Animal studies attempting to elicit lung cancer as a result of ETS exposure have failed.

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